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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/330,909	06/11/1999	JON A. WOLFF	MIRUS.011.01	1001

7590 02/24/2003
MARK K JOHNSON
P O BOX 510644
NEW BERLIN, WI 531310644

EXAMINER

WOITACH, JOSEPH T

ART UNIT PAPER NUMBER

1632

DATE MAILED: 02/24/2003

27

Please find below and/or attached an Office communication concerning this application or proceeding.

File

Office Action SummaryApplication No.
09/330,909Applicant(s)
Wolff, J. A. et al.Examiner
Joseph WeitachArt Unit
1632**-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --****Period for Reply**A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on Nov 14, 2002
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1, 2, 4-6, 12-14, 16-18, and 20-22 is/are pending in the application.
- 4a) Of the above, claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1, 2, 4-6, 12-14, 16-18, and 20-22 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claims _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on Jun 11, 1999 is/are a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

*See the attached detailed Office action for a list of the certified copies not received.

- 14) ☒ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- | | |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s). _____ | 6) <input type="checkbox"/> Other: |

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Continued Examination Under 37 CFR 1.114

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on November 14, 2002, paper number 23, has been entered.

DETAILED ACTION

This application claims benefit to provisional applications 60/100,168, filed September 14, 1998.

Applicants amendment filed November 14, 2002, paper number 24, has been received and entered. Claims 1 and 18 have been amended. Claims 1, 2, 4-6, 12-14, 16-18, 20-22 are pending and currently under examination.

Response to Amendment

The declaration of Dr. Jon Wolff filed on January 30, 2003, paper number 26, under 37 CFR 1.131 has been considered but is ineffective to overcome the 35 USC 102(e) rejection made over the Mann *et al.* reference.

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Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 16, 17 and 19 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Specifically;

Claims 16 and 17 are dependent on claim 15, however claim 15 was canceled in Applicants' amendment filed May 3, 2002, paper number 19. The claims are unclear because they are dependent on a canceled claim, and it is unclear what the claims encompass or to which independent claim(s) it refers. Amending the claims to be dependent on a pending claim or amending the claims to be independent claims would obviate the basis of the rejection. For the sake of compact prosecution, the claims will be interpreted to encompass all the limitations of claim 15.

Claim 19 is confusing and unclear in the recitation of 'wherein inserting the nucleic acid comprises injecting the nucleic acid' because claim 18 as newly amended recites 'injecting a solution containing nucleic acids'. The action of the nucleic acid being inserted does not have adequate antecedent basis in claim 18 where only the injector is inserted in step (b), and the

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limitation of injecting does not further limit claim 18 because this is specifically recited in amended claim 18 step (c).

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless --

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 1, 2, 4-6, 12-14, 16-18, 20 rejected under 35 U.S.C. 102(e) as being clearly anticipated by Isner *et al.* (US patent # 5,830,879) is withdrawn.

The amendments to the claims are noted. Isner *et al.* teach delivery and the expression of a nucleic acid by means of pressure, however the pressure is not hydrostatic as required by the instant claims. Rather, Isner *et al.* teach that the polynucleotide should be supplied on the surface of the delivery vehicle and the vehicle applied to the surface of the site of interest. The amendments to the claims have differentiated the instantly claimed invention from that disclosed in Isner *et al.*

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Claims 1, 2, 4-6, 12-14, 16-18, 20-22 are rejected under 35 U.S.C. 102(e) as being clearly anticipated by Mann *et al.* (US patent # 5,922,687) for the reasons below and as set forth in the previous office actions (papers number 5, 12, 17 and 21).

First, with respect to the declaration of Dr. Jon Wolff filed on January 30, 2003, paper number 26, under 37 CFR 1.131, the declaration has been fully considered but is ineffective to overcome the 35 USC 102(e) rejection made over the Mann *et al.* reference. Specifically, the instant claims are encompass delivery to the heart, however the declaration provides evidence of delivery through the portal vein (example 1) and as specifically to the liver (second and third examples). In the instant case, the declaration shows the method was practiced in a different organ. Additionally, the present claims specifically recite providing hydrostatic pressure, however there is no evidence that this was practiced in any of the examples in the declaration. Further, the second example indicates that invasive methods for clamping the liver vein were practiced, which is more invasive the present claims would encompass.

Mann *et al.* teach a method of delivering a nucleic acid into the heart by establishing an incubation pressure which facilitates the uptake of nucleic acid by the cell. As noted by Applicants some of the devices taught by Mann *et al.* would be invasive, however Mann *et al.* also teach a less invasive means encompassing delivery between two occlusions created by a double balloon catheter (see figure 4B), and more generally to any organ by providing the catheter for the pressurized delivery to the organ (see figures 5A and B). Additionally, while

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Mann *et al.* discuss the use of a protective sheath to help counteract the increased internal pressure, Mann *et al.* demonstrate that the method can be practiced without the protective sheath and achieve the same effective delivery (see figure 7B). Mann *et al.* teach that increasing pressure increases delivery efficiency (see figure 7C).

Claims 1, 2, 4-6, 12-14, 16-18, 20-22 rejected under 35 U.S.C. 102(a/e) as being clearly anticipated by Wolff *et al.* (US patent # 5,693,622) is withdrawn.

The amendments to the claims has differentiated the instantly claimed invention from that disclosed by Wolff *et al.* Specifically, the methods of Wolff *et al.* encompass the direct injection into the heart muscle and the cells of said muscle, not the delivery through a blood vessel.

Conclusion

No claim is allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Joseph Woitach whose telephone number is (703)305-3732.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Deborah Reynolds, can be reached at (703)305-4051.

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Any inquiry of a general nature or relating to the status of this application should be directed to the Group analyst Dianiece Jacobs whose telephone number is (703) 308-2141.

Papers related to this application may be submitted by facsimile transmission. Papers should be faxed via the PTO Fax Center located in Crystal Mall 1. The faxing of such papers must conform with the notice published in the Official Gazette, 1096 OG 30 (November 15, 1989). The CM1 Fax Center numbers are (703)308-4242 and (703)305-3014.

Joseph T. Waitach

A handwritten signature in cursive script that reads "Joe Waitach".

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